

Delaware Medicaid Program To Be Reimbursed Almost \$900K for Overcharges on EpiPens

The Medicaid Fraud Control Unit of the Delaware Department of Justice will join the United States and other states to settle allegations against Mylan Inc. and its wholly-owned subsidiary, Mylan Specialty L.P. (collectively "Mylan"). The settlement will resolve allegations that Mylan knowingly underpaid rebates owed to the Medicaid program for the drugs EpiPen and EpiPen Jr. ("EpiPen") dispensed to Medicaid beneficiaries. As part of the settlement, Delaware will receive \$899,882 in restitution and other recovery, which will be returned to the Delaware Medicaid program.

The allegations against Mylan were that it was misstating the nature of its EpiPen drug and mischaracterizing the price at which it sold the EpiPen, in order to reduce the amount of rebates that it was required to pay state Medicaid programs.

"This settlement will relieve some of the budget pressure on the state's Medicaid program in the coming year," Attorney General Matt Denn said. "We will continue to expand our efforts to work with our law enforcement colleagues to ensure that people do not take advantage of the state's largest health care program."

Mylan Specialty owns the exclusive rights to sell EpiPen in the United States and possesses legal title to the New Drug Codes ("NDCs") for EpiPen. The federal Medicaid Drug Rebate Statute requires participating pharmaceutical manufacturers or NDC holders, such as Mylan, to sign a Rebate Agreement with the Secretary of the United States Department of Health and Human Services as a precondition for obtaining Medicaid coverage for their drugs and to pay quarterly rebates to State

Medicaid programs for drugs dispensed to Medicaid beneficiaries. NDC holders are required to provide information to CMS concerning their covered drugs. In particular, they have to advise CMS regarding the classification of a covered drug as an “innovator” or “noninnovator” drug, as the amount of rebates owed varies depending on the drug’s classification. The amount of the rebate also depends on pricing information provided by the manufacturer. For drugs classified as “innovator” drugs, NDC holders must report their “Best Price,” or the lowest price for which it sold a covered drug in a particular quarter.

Specifically, the settlement resolves allegations that from July 29, 2010 to March 31, 2017, Mylan submitted false statements to the Centers for Medicare and Medicaid Services (“CMS”) that incorrectly classified EpiPen as a “noninnovator multiple source” drug, as opposed to a “single source” or “innovator multiple source” drug. Mylan also did not report a Best Price to CMS for EpiPen, which it was required to do for all “single source” and “innovator multiple source” drugs. As a result, Mylan submitted or caused to be submitted false statements to CMS and/or the states relating to EpiPen for Medicaid rebate purposes, and underpaid its EpiPen rebates to the state Medicaid Programs.

Deputy Attorney General Tiphany Miller and Senior Auditor Ellen Yates worked on the case for Delaware.

The investigation stemmed from two *qui tam* actions, *United States ex rel. sanofi-aventis US LLC v. Mylan Inc., et al.* (No. 16-cv-11572-ADB), and *United States ex rel. Ven-A-Care of the Florida Keys, Inc. v. Mylan Inc., et al.* (No. 17-10140-ADB), pending in the United States District Court for the District of Massachusetts. A *qui tam* case is one where an individual – known as a relator – claims to have specific knowledge of charges submitted for payment to the local, state or federal governments that are improper under federal or state False Claims Act laws; the federal, state or local

government can either intervene in the action and participate with the relator as a plaintiff, or the state can decline to intervene and allow the plaintiff/relator to attempt to recover those losses on behalf of the state.

The total amount Mylan will pay to the United States and the individual states is \$465 million.

Any Delawarean who suspects fraudulent billing or other fraud can report Medicaid Fraud by calling the Department of Justice Healthcare Provider Fraud Hotline at (302) 577-5000. Anonymous tips are accepted.